INVESTIGATIONAL AGENT STATUS REPORT	**REPORT SYMBOL MED 6710-10**

1. From: Clinical Research Department, Naval Medical Center, 34800 Bob Wilson Drive, San Diego, CA 92134-5000
To: Commanding Officer, Naval School of Health Sciences (ATTN: Clinical Investigation Program, (Code OP6)), Bethesda, MD 20889-5611
Via:

2. CIP/R&D PROJECT NO.

3. TITLE

4. INVESTIGATIONAL AGENT

5. REPORT TYPE

First report? ___ Yes ___ No
Second report? ___ Yes ___ No
Adverse event report? ___ Yes ___ No

6. PROJECT STATUS

Column A	**Column B**	**Column C**
__ Emergency Use-one patient only	**__ Drug or device used**	**__ Protocol active**
__ Ongoing approved protocol	**__ Drug or device not used**	**__ Protocol completed**
		__ Protocol abandoned

__ Drug has received FDA approval (Date of FDA approval _____)

7. PRIMARY EFFECT

___ No effect
___ Positive effect on the course of patient's condition
___ Undetermined effect
___ Adverse effect (Unusual in severity, timing, etc., or unanticipated, such as not listed in the informed consent. Specify below.)

Enclosure (6)

8. SIDE EFFECTS

___ None noted ___ Unlikely ___ Possible

___ Probable relation to investigational agent
___ All side effects were explained within the consent form
___ Side effects were unanticipated and not explained with the informed consent. (Specify below, attach a copy of the revised CPHS-approved consent form which indicates the new side effects, and complete section 9.)

9. REPORT OF ADVERSE PRIMARY SIDE EFFECTS

___ No adverse events

a. Date adverse effects were reported to:

CPHS _____
Drug Sponsor _____
FDA _____
NSHS _____

b. Adverse effects occurred, but were not reported. (Explain why they were not reported.)

10. DATE OF MOST RECENT PROTOCOL REVIEW BY THE CPHS

11. SIGNATURE AND GRADE OF PRINCIPAL INVESTIGATOR	**DATE**